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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,777	10/23/2000	Luis Angel Pardo-Fernandez	MPG-8	8515

7590 07/16/2002

Jane A Massaro  
Fish & Neave  
1251 Avenue of the Americas  
New York, NY 10020-1104

EXAMINER

WEGERT, SANDRA L

ART:UNIT PAPER NUMBER

1647

DATE MAILED: 07/16/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/694,777

Applicant(s)

PARDO-FERNANDEZ ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,14,15,32 and 34-44 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1,3-5 and 15 is/are rejected.

- 7) ☒ Claim(s) 6-10, 14, 32, and 34-44 is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

The Declaration of Dr. Pardo-Fernandez under 37 CFR 1.132, filed 3/19/02, and the Information Disclosure Statement, submitted 3/19/02 (Paper 15) have been entered. The Amendment filed 1 April 2002 has been entered as Paper 16. Claims 2, 11, 12, 13, 16-31 are canceled. Claims 34-44 were added and read primarily on the elected invention. Claims 1, 3-10, 14, 15, 32 and 34-44 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Withdrawn Objections and/or Rejections**

#### ***Title***

The objection to the title as set forth at p. 3 of the previous Office, 19 Dec 2002 (Paper No. 13), is *withdrawn* in view of the amendment which introduced a new title (Paper 16, 1 April 2002).

#### ***Sequence Rules***

The objection to the specification for not being in compliance with the sequence rules is *withdrawn* in view of the amendment which introduced SEQ ID NO's into the specification (Paper 16, 1 April 2002).

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***Claim Objections-***

The objections to claims 1 and 8 for reciting non-elected inventions, as set forth at p. 4 of the previous Office Action, 19 Dec 2002 (Paper No. 13), is *withdrawn* in view of the explanation by the Applicant that the recited sequences are splice variants of one another (Paper 16, 1 April 2002).

***Claim Rejections - 35 USC § 102***

The rejection of claims 1, 3-9 and 10 under 35 U.S.C. 102(b) for being unpatentable over Warmke, et al (1994, PNAS., 91:3438-3442; see Fig 1) is *withdrawn* in view of the amendment by the applicant which amended the claims to recite strict hybridization protocols (Paper 16, 1 April 2002).

***35 USC § 112, first paragraph***

The rejection of Claims 1-10, 14, 15 and 32 under 35 U.S.C. 112, first paragraph, as set forth at p. 4-5 of the previous Office Action, 19 Dec 2002 (Paper No. 13), because the claims did not recite stringency requirements and thus read on multiple undefined sequences, is *withdrawn* in view of the amendment inserting stringency data into independent claims (Paper 16, 1 April 2002).

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**Objections and/or Rejections**

***Claim Objections-***

Claims 6-10, 14, 32 and 34-44 are objected to for depending from a rejected base claim (see below).

Claims 14, 15, 32, 34, 42, 43 and 44 are objected to because they recite or encompass non-elected inventions (e.g., "polypeptide" and "antibody"). The reasons for this rejection for claims 14, 15 and 32 are set forth at p. 4 of the previous Office Action, 19 Dec 2002 (Paper No. 13).

***35 USC § 101, - non-statutory***

35 U.S.C. 101 reads as follows:

**Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

Newly-amended claims 1 and 3-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims read on a product of nature in that the claimed polynucleotide is not isolated or modified. Amending the claims to read "isolated" or "recombinant", etc. would be remedial.

***35 USC § 112, first paragraph***

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Claim 15 is not enabled by the specification because the subject matter was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for the limitation of the claims wherein a composition comprising a nucleic acid, polypeptide or antibody is used in *diagnosis*.

Claims 15 reads on a composition for diagnosis comprising the nucleic acids, polypeptides, or antibodies recited in previous claims. Claim 15 recites use of a composition of nucleic acids, polypeptides, and/or antibodies for *diagnosis*. There is no enabling discussion or working examples disclosed in the instant application as to how or what disease is related to the *eag* K<sup>+</sup> channel disclosed in the specification, nor is there discussion of how one would practice the method of diagnosing a particular disease. The Declaration under 37 CFR 1.132, submitted 3/29/02, demonstrates that the *eag* K<sup>+</sup> channel of the instant application is expressed in numerous tissues, including most cancerous tissues tested. Applicants suggest that the polynucleotide can be used to diagnose a proliferative disease, such as: cancer, a neurodegenerative disease, or psoriasis (page 19, 3/29/02). Applicants argue that one of ordinary skill in the art would know how to diagnose a disease related to cellular proliferation using the *eag* K<sup>+</sup> channel of the instant application.

Applicant's arguments have been considered, but are not deemed to be persuasive. Diagnosis of a disease requires proper *identification* of the disease being diagnosed, rather than, for example, any *diseases related to cellular proliferation*.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation required to determine how to use the disclosed sequences

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to diagnose a condition, the lack of direction or guidance in the specification regarding the same, the lack of working examples that identify or diagnose a particular condition, the state of the art which is silent concerning diseases related to this channel, and the breadth of the claim which embraces potentially many diseases --undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

***Conclusion***

Claims 6-10, 14, 15, 32, and 34-44 are objected to.

Claims 1, 3-5 and 15 are rejected.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

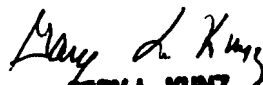
***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

6/18/02

  
**GARY L. KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1000**